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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,547	04/26/2001	Michael A. Adams	PTQ-0031	7618

20350 7590 06/28/2002

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/28/2002 *10*

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/842,547</b>	Applicant(s) <b>Adams et al.</b>
Examiner <b>Pak, J.</b>	Art Unit <b>1616</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_.

2a)  This action is **FINAL**. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-32 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6)  Other: \_\_\_\_\_

Claims 1-32 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 13-22, drawn to method for inhibiting and preventing a malignant cell phenotype, method for treating cancer, comprising administering a low dose of a nitric oxide mimetic, classified in various classes and subclasses such as 514/509 for nitroglycerin, 514/492 for sodium nitroprusside, 514/364 for molsidomine, and various other classifications depending on the particular structure of the mimetic.
- II. Claims 9-12, drawn to a formulation comprising a nitric oxide mimetic, classified in various classes and subclasses such as 514/509 for nitroglycerin, 514/492 for sodium nitroprusside, 514/364 for molsidomine, and various other classifications depending on the particular structure of the mimetic.
- III. Claims 23-25, drawn to method for prophylactically inhibiting and prevent a malignant cell phenotype in animals *at high risk for developing cancer* comprising administering a low dose of a nitric oxide mimetic, classified in various classes and subclasses such as 514/509 for nitroglycerin, 514/492 for sodium nitroprusside, 514/364 for molsidomine, and various other classifications depending on the particular structure of the mimetic.
- IV. Claims 26-29, drawn to method of monitoring or diagnosing the progression of a tumor in a patient comprising measuring a level of a tumor marker in the presence of a low dose of a nitric oxide mimetic, classified in various classes and subclasses

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such as 600/309+, 514/509 for nitroglycerin, 514/492 for sodium nitroprusside, 514/364 for molsidomine, and various other classifications depending on the particular structure of the mimetic.

Claims 30-32 are directed to the non-statutory subject matter of “use” of nitric oxide mimetics, and therefore, said claims cannot be placed in any invention groups for restriction purposes.

Applicant is **further required** to elect for examination purposes a single disclosed species of a nitric oxide mimetic, such as nitroglycerin or molsidomine. To be clear, this means applicant is required to first elect one of the invention groups I, II, III or IV, and then further elect a single disclosed species of a nitric oxide mimetic.

The four inventions as set forth above are distinct from the other inventions for the following reasons. The formulation invention of Group II is distinct over the method invention of Group I because the formulation can be used in a materially distinct method, such as in the treatment of acute anginal pain or myocardial infarction. Group III invention is independent and distinct over the other inventions because it is a prophylactic method wherein high risk animals are selected to treatment. Group IV invention is independent and distinct over the other inventions because a monitoring and diagnostic method is a separate subject for inventive effort from treatment methods.

Additionally, a search and examination of the application would place an undue burden on the Examiner if the restriction were not required. Given the breadth and divergence of various

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“nitric oxide mimetic,” scope of “malignant cell phenotype” and cancer treatments, search and examination of just one of the invention groups would already place a serious burden on the Examiner.

Consequently, for the reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

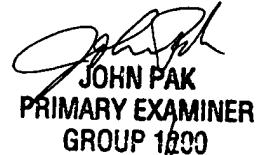
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600